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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 09/775,648  | 02/05/2001  | Toshiaki Takezawa    | 202785US0X              | 3290             |
| 22850   | 7590        | 01/14/2003           |                         |                  |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | EXAMINER                |                  |
|   |             | MARVICH, MARIA       |                         |                  |
|   |             | ART UNIT             | PAPER NUMBER            |                  |
|   |             | 1636                 | 8                       |                  |
|   |             |                      | DATE MAILED: 01/14/2003 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                  |                  |
|------------------------------|----------------------------------|------------------|
| <b>Office Action Summary</b> | Application No.                  | Applicant(s)     |
|                              | 09/775,648                       | TAKEZAWA ET AL.  |
|                              | Examiner<br>Maria B Marvich, PhD | Art Unit<br>1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-31 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

This office action is in response to an amendment filed 10/28/02. Claims 1-10 have been amended and claims 11- 31 have been added.

***Response to Amendment***

The substitute specification submitted (10/28/02) has been received. However, amendments to the specification do not put the specification in proper idiomatic English and therefore the substitute specification will not be entered.

Objection to claims 4,5,6 and 9 are withdrawn in light of amendment of these claims.

***Specification***

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8, 10, 11, 13, 17-19, 24-26 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Spaulding et al., US patent 6,001,643.

Spaulding et al. teach use of a hydrodynamic cell culture environment comprised of a tissue culture chamber for three dimensional tissue growth (abstract and column 9, line 44-57). Spaulding teaches use of a chamber for fertilization and development of embryos (column 20, line 29-56). For this use, the chamber contains endometrial tissue for co-culturing the fertilized egg. The chamber is formed from a variety of materials such as polystyrene or polycarbonate or nylon (column 7, line 50-64). This chamber is then placed in a culture vessel (abstract) to allow for the development of the fertilized ovum.

Given the definition that a cell incorporated type three-dimensional reconstructed tissue" is a "a scaffold for growing three-dimensional tissue derived from fertilized ovum", the invention of Spaulding et al. meet the limitations of the instant claim in that a scaffold for the adhesion and three-dimensional growth of a fertilized ovum is disclosed

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 11-21 by dependency are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Use of the phrase "derived from animals selected from the group consisting of cell, tissues and organs" in claim 2 is unclear as animals cannot be selected from the group consisting of cells, tissues and organs.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-18, 22-25 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a carrier characterized in that cells of the cell incorporated type three-dimensional reconstructed tissue are derived from epithelial and stromal endometrial cells from a bovine uterus (page 18, line 9-16), does not reasonably provide enablement for cell incorporated type three-dimensional reconstructed tissue in which the carrier is derived from any of cells, tissue or organs from any animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. For reason put forth in the first office action and below in response to applicant's arguments, the claims are rejected.

#### *Response to Arguments*

Applicants traverse 112, first paragraph, rejection of claims 2, 3, 7 and 8 and the 112, first paragraph rejection of claims 1-3, 7 and 8 in paper number 8 pages 7-10. Applicant argues that due to the disclosures in patent number 5,985,539 and 5,763,399 as

well as Japanese Patent no. 3081130, a person of skill in the art would be able to, with specification in hand, perform the instantly claimed invention. Specifically, applicant describes that a basic technology of tissue engineering with cotton gauze as a support and extracellular matrices that include collagen, fibronectin, vitronectin, laminin, proteoglycam and glycosaminoglycan is provided in the specification and the art. Furthermore, applicant argues that a "cell incorporated type three dimensionally reconstructed tissue" is defined in the specification as "a scaffold for growing three-dimensional tissue derived from fertilized ovum".

The rejection of claims based upon 112, first paragraph, stands as the specification teaches a carrier characterized in that cells of the cell incorporated type three-dimensional reconstructed tissue are derived from epithelial and stromal endometrial cells from a bovine uterus (page 18, line 9-16), but does not teach a cell incorporated type three-dimensional reconstructed tissue in which the carrier is derived from any of cells, tissue or organs from any animal. Any cell, tissue or organ from any animal is not enabled for use of the invention for reasons set forth in the first office action, paper number page 4-7. Furthermore, the specification points out (page 7, line 17-page 8, line 7) the cells can be homogeneous or heterogeneous, primary cultured cells, strained cells or cells transfected with an exogenous gene. "In particular, in the case of preparing the cell incorporated type three-dimensionally reconstructed tissues as an implantation model of the fertilized ovum into an endometrium, the cells to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue are preferably cell derived from an endometrium, particularly endometrial epithelial cells and

stromal cells". Therefore, it is maintained that the invention is not enabled for use with any cells, tissue or organs from any animal.

The rejection of claims based upon 112, first paragraph, that the specification provides support for an extracellular matrix or for the use of any natural or synthetic thread in the mesh network that is bioabsorptive has been reconsideration based upon applicants arguments and reconsideration of the prior art based upon the applicants arguments. The applicant points to the art that illustrates cotton gauze and sterile gauze, also used in the instant application, to form a mesh network for the formation of three-dimensional organs. As well, Spaulding et al. (US patent 6,001,643) use nylon in constructing three-dimensional organs. While collagen gels represent the majority of matrices used for tissue engineering, it is appreciated that a variety of extracellular matrices such as those listed in the applicants arguments can be used such as vitronectin, laminin, and fibronectin.

No claims are allowed.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4242 for regular communications and (703) 305-4242 for After Final  
communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is (703) 305-  
3553.

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

January 13, 2003

DAVID GUZO  
PRIMARY EXAMINER  
